Premarket Notification [510(k)] Summary

OCT 19 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K121845

Company: DYN'R SAS
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Contact Person: Tim LAWTON

Date Prepared: 22nd June 2012

Device Names:

Trade/Proprietary Name:	**SDX System with Automatic Gating Module**
Common or Usual Name:	**Patient Breathing Control system**
Device Class:	**Class II**
Classification Name:	**21 CFR §892.5050**
Product Code:	**IYE : Accessory to Medical Charged Particle Radiation Therapy system** **LHN : System, Radiation Therapy, Charged-Particle, Medical**

Substantial Equivalence:
The data and information supplied in this submission demonstrates substantial equivalence to two predicate devices :

- Varian Medical Systems, Inc – RPM Respiratory Gating System with respect to the Gating aspects only (Table 1)
- Dyn'R SAS – SDX Module without the Automatic Gating Module (Table 2)

TABLE 1	Predicate device (K102024)	New Device
Device Name	RPM* * Gating part only of the RPM System	SDX System with Automatic Gating Module
510(K) owner	Varian Medical Systems, Inc	Dyn'R SAS

TABLE 1	Predicate device (K102024)	New Device
Device Name	RPM* * Gating part only of the RPM System	SDX System with Automatic Gating Module
Common or usual name		Radiotherapy breathing control
Product Code	IYE Accelerator, Linear, Medical LHN System, Radiation Therapy, Charged-Particle, Medical	Same
Intended use	-- The RPM Respiratory Gating System is used to obtain tracking of the subject respiratory pattern for respiratory synchronized image acquisition and radiation therapy treatment.	SDX is intended for use in Radiation therapy as an aid in allowing the patient and treatment staff to visualize a patients breathing process and to optimize breathing to limit internal motion during imaging & treatment. The SDX System including the Automatic Gating Module is used to provide respiratory synchronization for radiation therapy imaging & treatment.
Gating requirements	May be gated with radiation therapy treatment systems possessing an External System Gating Interface	Same
Radiation therapy treatment systems	Conventional linear accelerators Proton therapy systems Radiation therapy simulators Image acquisition devices	Same Same N/A Same
Impact on Radiation therapy treatment systems	Does not change the intended diagnostic or therapeutic effect	Same
Approach	Characterize the patients respiratory motion information to synchronize operation with the respiratory motion	Same
Application	Used in image acquisition & radiation treatment	Same
	Triggering the image acquisition	Same
	Respiratory motion signal to : - trigger beam-hold - limit the beam-on time	Same

TABLE 2	Predicate device (K092479)	New Device
Device Name	SDX	SDX System with Automatic Gating Module
510(K) owner	Dyn'R SAS	Same
Intended Users	Healthcare Licensed practitioner	Same
Technology used	Spirometer with visual feedbacks	Same
Principle	Measuring and tracking of patient tidal volumes	Same
Patient Population	Patient requiring radiation therapy treatment of tumour in the abdominal-thoracic region influenced by respiration	Same
Place of use		
SDX Module	Used in the scanner room, simulation room and accelerator room	Same
Automatic Gating Module	N/A	Control Room Connected between Dedicated Workstation & the radiation therapy treatment system possessing an External System Gating Interface
Role during radiation therapy process	Aid the operator to pause patient breathing at a precisely indicated tidal volume and coordinate treatment delivery and image acquisition with this pause	Aid the operator to optimize a patient breathing and to provide respiratory synchronization for image acquisition & treatment delivery
Operator involvement	-	-
Image acquisition process	Operator triggered N/A	Same Automatic Gating Module triggered
Radiation treatment process	Operator triggered N/A	Same Automatic Gating Module triggered

Description:
The SDX Systems are intended to be used in conjunction with a Radiation Therapy systems (imaging & treatment) requiring operator intervention to start & stop radiation.

The Automatic Gating Module is intended to facilitate the interface between operators, whilst ensuring at all times the operators have complete control & maintain the final decision in imaging & treatment.

The Automatic Gating Module provides the direct interface between the SDX Module and the Imaging / Radiation Treatment equipment; providing channels on :

- device communication / identification
- recommendation to start Patient Imaging / Radiation
- order (or recommendation) to stop patient Imaging / Radiation

The Automatic Gating Module is connected, via cabling, to the Radiation Therapy systems via their own "external interfacing equipment".

The use of the Automatic Gating Module allows the SDX to optimize breathing to limit internal motion during imaging & treatment independent to the breathing method chosen, Breath Hold, Free Breathing, etc.
Thus patients breathing pattern allows the selection of the gating levels, facilitate the starting & stopping of the radiation beam between the two defined levels.

Intended Use :
SDX is intended for use in Radiation therapy as an aid in allowing the patient and treatment staff to visualize a patients breathing process and to optimize breathing to limit internal motion during imaging & treatment.

The SDX System including the Automatic Gating Module is used to provide respiratory synchronization for radiation therapy imaging & treatment.

Discussion of Performance Data:
The addition of the Automatic Gating Module to the SDX System has not resulted in a modification of the systems performance with respect to the elements provided in the initial 510(k) submission : K092479 ; thus no system performance testing has been carried out.

The SDX System with the Automatic Gating Module has been tested and is conform to IEC 60601-1 Electrical Safety of Medical Electrical Device and IEC 60601-1-2 Electro-Magnetic Compatibility of Medical Electrical Device

Performance Testing of the Automatic Gating Module has been conducted to demonstrate conformance to the required specifications of the Radiotherapy device manufacturers, covering both safety & functionality criteria.

Conclusion for Performance Testing :
The performance testing conclude that the safety and effectiveness of the devices is not compromised and that it meets all acceptance criteria, demonstrating that the device can be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

Mr. Tim Lawton
Regulatory Affaires Manager
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Re: K121845
Trade/Device Name: SDX System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, LHN
Dated: September 10, 2012
Received: September 12, 2012

Dear Mr. Lawton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121845

Device Name: SDX System

Indications for Use:

SDX is intended for use in Radiation therapy as an aid in allowing the patient and treatment staff to visualize a patients breathing process and to optimize breathing to limit internal motion during imaging & treatment.

The SDX System including the Automatic Gating Module is used to provide respiratory synchronization for radiation therapy imaging & treatment.

The SDX System may be used for pediatric, adolescents & adult patients above the age of 5 years capable of understanding and following the radiotherapists instructions.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K121845